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Application for Patent

אני, (שם, המבקש, מענו ולגבי גוף מאוגד - מקום התאגדותו)
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הממציא: אבידור שולמן

mer, by virtue of

the Law

הדין

בעל אמצאה מכח

invention the title of which is

ששמה הוא

Hebrew)

(בעברית)

תחליף לפוספוליפידים של חלב אם כתוסף מזון

(באנגלית)

English)

HUMAN BREAST MILK PHOSPHOLIPID MIMETIC AS DIETARY SUPPLEMENT

hereby apply for a patent to be granted to me in respect thereof.

מבקש בזאת כי ינתן עליה פטנט

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16647/ph/03

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**HUMAN BREAST MILK PHOSPHOLIPID MIMETIC
AS DIETARY SUPPLEMENT**

Field of the Invention

The present invention relates to the field of nutritional foods, or food supplements, aiming to provide the population with ingredients that will assist in maintaining a well balanced diet and prevent and/or treat health disorders related to the lack thereof.

Background of the Invention

All publications mentioned throughout this application are fully incorporated herein by reference, including all references cited therein.

Lipids in general are the building blocks of life. They are used as building blocks of membranes, cells and tissues, as energy sources, either immediate or stored, as precursors to a variety of other bio-molecules, as well as biochemical signals. In all biochemical processes lipids have an important role.

Many lipids, and especially triglycerides, are consumed in the human nutrition on a daily basis. In most cases, these lipids are metabolized and used for energy storage, precursors for biosynthesis of other lipids or bio-molecules. Whatever the fate of the lipids in the metabolic pathways, during and after their consumption, they interact with other nutrients or their metabolic products.

Nutrients in human breast milk, however, are carried in fat globules designed to deliver these nutrients and make them bio-available to the infant. These globules are constructed of lipids, among them phospholipids.

In contrast, lipids in the form of fatty acids hydrolyzed from triglycerides interact with calcium ions, either obtained from the diet or present in the body. This interaction can lead, in some cases, to the complexation of fatty acids and calcium ions to form insoluble complexes, which cannot be utilized

by the human body and are secreted, resulting in the loss of calcium ions and fatty acids. This is actually a loss of important nutrients, since calcium is essential for skeleton building and other bodily functions, while fatty acids are an important source of energy and precursors of other lipids and nutrients.

Thus, infants and young children until the age of 3 are advised to base their nutrition on human breast milk or its replacements in the form of infant formulas, since these include in their ingredients a fat portion which mimics to some extent the fat composition of human breast milk. However, many infants and young children do not have access to such fat, either because they do not breast feed or consume infant formulas, or they consume infant formulas without human milk fat replacements, or even, above a certain age, because they supplement their nutrition with other foods, besides breast milk or infant formula. Moreover, many food products allegedly designed for the consumption of infants and young children, such as cereals and biscuits, are based on vegetable oils which have nothing in common with breast milk fat.

In all these scenarios, infants and young children consume fats and oils which upon their digestion create insoluble complexes with essential calcium which in turn are secreted, leading to the loss of both calcium and energy supplying lipids. This is very detrimental, since calcium is an essential nutrient during child development, in particular for skeletogenesis, i.e., bone formation.

For adults, dietary supplementation of calcium is carried out using commercial products in which the calcium is in the form of calcium carbonate, calcium alginate, calcium picolinate, calcium from corals, and many other forms. In many cases, this supplemented calcium is not absorbed by the body and is secreted, or it causes digestive problems, such as constipation.

Therefore, although the dietary supplementation of calcium is needed for infants and young children, as well as adults, especially women over the age of 45, in order to treat or prevent disorders or conditions caused by calcium depletion, it is not fulfilled in a satisfactory manner.

Thus, it is an object of the present invention to provide a dietary ingredient, in the form of a mimetic substitute of human breast milk lipid, aimed especially for adult and young children consumption, which enhances calcium absorption. Other uses and objects of the invention will become clear as the description proceeds.

Summary of the Invention

In a first aspect, the present invention provides a dietary ingredient comprising an edible lipid, wherein said edible lipid is a mimetic substitute of human breast milk, having the property of enhancing the absorption of calcium.

The main property of the dietary ingredient of the invention is its ability to enhance the absorption of calcium. Said calcium may be provided by other foods, or it may be obtained in admixture with the dietary ingredient of the invention.

Thus, in one embodiment, the dietary ingredient of the invention may optionally further comprise calcium.

In another embodiment, the dietary ingredient of the invention can optionally include other nutrients, such as other minerals or vitamins, or a combination of both.

The dietary ingredient of the invention shall be used in the preparation of any food product which contains fat as one of its ingredients or components.

Thus, the dietary ingredient of the invention may replace all fat content of the food product.

This food product may be aimed and consumed by infants and young children, such as formula, biscuits, candy, bars, cereals, instant drink products, prepared cooked mashed vegetables and/or fruits, etc.

Alternatively, this food product is any food product, such as dairy products, ice cream, biscuits, soy products, pastry and bread, sauces, condiments, oils and fats, margarines, spreads, cereals, drinks and shakes, infant formulas and foods, bars, snacks, candies or chocolate products. Thus, the dietary ingredient provided by the invention is to be included in food products for adult consumption.

In another aspect, the dietary ingredient of the invention is intended for use in the prevention and/or treatment of disorders associated with depletion of bone calcium or conditions related to decrease in bone density.

In a further aspect, the dietary ingredient of the invention is also intended for use in the enhancement of bone formation.

Thus, lastly, the present invention provides a dietary ingredient for use in the enhancement of energy intake by infants and children.

Detailed Description of the Invention

The present invention describes food products based on a breast milk fat mimic that replaces most or all of the fats and oils used in the preparation and formulation of these food products.

In a first aspect, the present invention provides a dietary ingredient comprising an edible lipid, wherein said edible lipid is a mimetic substitute of

human breast milk, having the property of enhancing the absorption of calcium.

Lipids, under the scope of this invention, include phospholipids and their derivatives, triglycerides and derivatives, sterols, stanols, cholesterol, sphingolipids, ceramides, fatty acids, fatty alcohols, glycolipids, proteolipids, lipopolysaccharides, ether-lipids, polar and non-polar lipids, and all of their derivatives and sub-families.

Preferably, the lipid of the dietary ingredient of the invention is based on a synthetic oil (which can be produced both chemically and, preferably, enzymatically) which mimics the triglyceride composition of human breast milk fat. This oil has, preferably, a high level of Palmitic acid at the *sn*-2 position of the triglycerides, above 40%, and preferably over 65% of the total Palmitic acid. Furthermore, this oil has a high level of unsaturated fatty acids at *sn* positions 1 and 3, preferably over 50%. This ingredient is manufactured by Enzymotec, under the name **InFat** (Enzymotec Ltd., Migdal HaEmeq, Israel).

The unique structure of **InFat** results in the release of the unsaturated fatty acids from the *sn*-1 and 3 positions. These fatty acids either do not generate, or generate in very small amounts, indigestible calcium complexes, hence not causing the loss of both calcium and energy. The glycerides with the Palmitic acids play other important roles in the nutrition of infants.

Therefore, the absorption of calcium is not adversely affected, as may be with other types of fats and oils.

The main property of the dietary ingredient of the invention is its ability to enhance the absorption of calcium. Said calcium may be provided by other foods, or it may be obtained in admixture with the dietary ingredient of the invention.

Thus, in one embodiment, the dietary ingredient of the invention may optionally further comprise calcium.

In another embodiment, the dietary ingredient of the invention can optionally include other nutrients, such as other minerals or vitamins, or a combination of both.

The present invention also teaches a method of preparation of the dietary ingredient of the invention, comprising admixing an edible lipid, and optionally calcium, and at least one of additives, emulsifiers or carriers, wherein said edible lipid is a mimetic substitute of human breast milk.

The dietary ingredient of the invention shall be used in the preparation of any food product which contains fat as one of its ingredients or components. Thus, the dietary ingredient of the invention may replace all fat content of the food product.

This food product may be aimed and consumed by infants and young children, such as formula, biscuits, candy, bars, cereals, instant drink products, prepared cooked mashed vegetables and/or fruits, etc.

Alternatively, this food product is any food product, such as dairy products, ice cream, biscuits, soy products, pastry and bread, sauces, condiments, oils and fats, margarines, spreads, cereals, drinks and shakes, infant formulas and foods, bars, snacks, candies or chocolate products. Thus, the dietary ingredient provided by the invention is to be included in food products for adult consumption.

In another aspect, the dietary ingredient of the invention is intended for use in the prevention and/or treatment of disorders associated with depletion of bone calcium or conditions related to decrease in bone density.

A significant percentage of the adult population, in particular pre- and post-menopause women, suffers from osteoporosis, a common disorder caused by hormonal-related depletion of calcium in the bones. Consequently, calcium supplements are the biggest selling supplement in the world. However, as described above, in many cases these calcium supplements do not supply this essential nutrient effectively, due to poor absorption and, in some cases, they may even cause digestive disorders.

Hence, the dietary ingredient of the invention aims to solve this problem, by providing the means, i.e., the lipids that allow and facilitate calcium absorption. Consequently, the consumption of food products based on **InFat** as the major, if not only, fat source will facilitate improved absorption of calcium either from food sources, or from calcium supplements.

The incorporation of a human milk fat lipid ingredient (**InFat**) in the dietary ingredient of the invention, together with calcium, will assist in its absorption and will prevent its secretion as insoluble or indigestible complexes, thus ensuring its bio-availability.

Additionally, the production of food products containing fats and/or oils based on the human milk fat lipid (**InFat**) comprised in the dietary ingredient of the invention shall motivate the general population to incorporate such products in their nutrition, in order to assist in the absorption and bio-availability of a variety of supplemented nutrients, especially calcium. This shall enhance the absorption and bio-availability of both supplemented and naturally occurring nutrients, preferably calcium, in the normal human nutrition.

In a further aspect, the dietary ingredient of the invention is also intended for use in the enhancement of bone formation.

As mentioned before, calcium is an important nutrient during child development, especially for proper skeletogenesis. Therefore, dietary supplements containing calcium should be an integral part of children's nutrition, preferably infants and children until the age of 3.

The enhanced absorption and bio-availability of nutrients will optimize their preservation and maximize the energy provided by the same. This enhanced absorption and bio-availability will also reduce disorders, such as digestive disorders, related to the loss of valuable nutrients.

The importance of calcium for the human body goes beyond skeletal development and the treatment or prevention of osteoporosis. Calcium is one of the most important minerals used by the organism to perform numerous biochemical processes. It is important in ion pump functions, as a co-factor for enzymes, as a cross-membrane potential mediator, etc. Thus, calcium depletion has an adverse effect on all these processes and functions of the body. Therefore, the dietary ingredient of the invention is highly recommended as a dietary supplement in the adult diet.

Thus, lastly, the present invention provides a dietary ingredient for use in the enhancement of energy intake by infants and children.

The present invention is defined by the claims, the contents of which are to be read as included within the disclosure of the specification.

Disclosed and described, it is to be understood that this invention is not limited to the particular examples, process steps, and materials disclosed herein as such process steps and materials may vary somewhat. It is also to be understood that the terminology used herein is used for the purpose of describing particular embodiments only and not intended to be limiting since the scope of the present invention will be limited only by the appended claims and equivalents thereof.

It must be noted that, as used in this specification and the appended claims, the singular forms "a", "an" and "the" include plural referents unless the content clearly dictates otherwise.

Throughout this specification and the claims which follow, unless the context requires otherwise, the word "comprise", and variations such as "comprises" and "comprising", will be understood to imply the inclusion of a stated integer or step or group of integers or steps but not the exclusion of any other integer or step or group of integers or steps.

The following Examples are representative of techniques employed by the inventors in carrying out aspects of the present invention. It should be appreciated that while these techniques are exemplary of preferred embodiments for the practice of the invention, those of skill in the art, in light of the present disclosure, will recognize that numerous modifications can be made without departing from the spirit and intended scope of the invention.

Examples

Example 1: Infant formula based on InFat.

An infant formula comprising **InFat** and additional oils and fats that mimic the human breast milk fat composition that facilitates enhanced calcium intake as well as improved energy preservation (in the form of free fatty acids). The **InFat** may be used as is or as a blend that would constitute about 25-40% of the formula and would replace most or all other fats and oils from the formula.

InFat is an oil containing over 90% triglycerides. **InFat** also contains diglycerides. In some formulations, **InFat** can include up to 3% free fatty acids. The triglycerides of this product are characterized by a high percentage

of palmitic acid at the *sn*-2 position, over 60%, from the total palmitic acid in this oil. The *sn*-1 and 3 positions are characterized by a high percent of oleic acid and other unsaturated fatty acids.

Example 2: Biscuits and pastry for infants and young children.

A biscuit or pastry product designed nutritionally for infants and young children. The biscuit has several percents of oils and fats, all or most are **InFat**, thus ensuring that while eating such biscuits or pastries the infant will not lose valuable calcium and energy. Such product may include 1 to 15% fat or oil, preferably 3 to 7%.

Example 3: Dairy products for infants and children for enhanced calcium intake.

A dairy product, such as yoghurt, designed nutritionally for infants and young children. The dairy product, such as yoghurt, has several percents of oils or fats, all or most are **InFat**, thus ensuring that while eating such dairy product the infant will not lose valuable calcium and energy. Such product may include 0.5 to 15% fat or oil, preferably 3 to 10%.

Example 4: Cereal products for infants and children for enhanced calcium intake.

A cereal product, such as oatmeal or rice cereal, designed nutritionally for infants and young children. The cereal product has several percents of oils or fats, all or most are **InFat**, thus ensuring that while eating such cereal product the infant will not lose valuable calcium and energy. Such product may include 0.5 to 15% fat or oil, preferably 2 to 7%.

Example 5: Mashed fruits and/or vegetables products for infants and children for enhanced calcium intake.

A mashed fruit or vegetable prepared food product designed nutritionally for infants and young children. The mashed fruit or vegetable prepared product has several percents of oils or fats, all or most are **InFat**, thus ensuring that

while eating such mashed food product the infant will not lose valuable calcium and energy. Such product may include 0.5 to 15% fat or oil, preferably 1 to 7%.

Example 6: Meat products for infants and children for enhanced calcium intake.

A mashed meat or soup prepared food product designed nutritionally for infants and young children. The mashed meat or soup prepared product has several percents of oils or fats, all or most are **InFat**, thus ensuring that while eating such meat product the infant will not lose valuable calcium and energy. Such product may include 0.5 to 15% fat or oil, preferably 3 to 10%.

Example 7: Condiment products for infants and children for enhanced calcium intake.

A condiment food product, such as ketchup for example, designed nutritionally for infants and young children. The condiment product, such as ketchup, has several percents of oils or fats, all or most are **InFat**, thus ensuring that while eating such condiment product the infant will not lose valuable calcium and energy. Such product may include 0.5 to 15% fat or oil, preferably 2 to 7%.

Example 8: Sweet spreads products for infants and children for enhanced calcium intake.

A sweet spread food product, such as chocolate spread, jam or peanut butter flavored spread, designed nutritionally for infants and young children. The sweet spread product has several percents of oils or fats, all or most are **InFat**, thus ensuring that while eating such sweet spread product the infant will not lose valuable calcium and energy. Such product may include 0.5 to 30% fat or oil, preferably 5 to 15%.

Example 9: Cooking oils/fats for infants and children for enhanced calcium intake.

A cooking oil or fat spread product designed nutritionally for infants and young children. The cooking oil or fat spread product has several percents of oils or fats, all or most are **InFat**, thus ensuring that while eating such oil or spread product the infant will not lose valuable calcium and energy. Such product may include 15 to 99% fat or oil, preferably 60 to 95%.

Example 10: Biscuits and pastry for adult nutrition for enhanced calcium intake.

A biscuit or pastry product designed nutritionally for adults. The biscuit has several percents of oils and fats, all or most are **InFat**, thus ensuring that while eating such biscuits or pastries the adult will not lose valuable calcium. Such product may include 1 to 15% fat or oil, preferably 3 to 7%.

Example 11: Dairy products for adult nutrition for enhanced calcium intake.

A dairy product, such as yoghurt, designed nutritionally for adults. The dairy product, such as yoghurt, has several percents of oils or fats, all or most are **InFat**, thus ensuring that while eating such dairy product the adults will not lose valuable calcium. Such product may include 0.5 to 15% fat or oil, preferably 3 to 10%.

Example 12: Cereals products for adults for enhanced calcium intake.

A cereal product, such as corn flakes and granola, designed nutritionally for adults. The cereal product has several percents of oils or fats, all or most are **InFat**, thus ensuring that while eating such cereal product the adults will not lose valuable calcium. Such product may include 0.5 to 15% fat or oil, preferably 2 to 7%.

Example 13: Meat products for adults for enhanced calcium intake.

A meat food product, such as sausage or hamburgers, designed nutritionally for adults. The meat product has several percents of oils or fats, all or most are **InFat**, thus ensuring that while eating such meat product the adults will not lose valuable calcium. Such product may include 0.5 to 25% fat or oil, preferably 3 to 10%.

Example 14: Prepared food products for adults for enhanced calcium intake.

A prepared food product, such as hamburgers, vegetable dishes, french fries, pizza, and alike, designed nutritionally for adults. The prepared food product has several percents of oils or fats, all or most are **InFat**, thus ensuring that while eating such prepared food product the adults will not lose valuable calcium. Such product may include 0.5 to 25% fat or oil, preferably 2 to 7%.

Example 15: Condiment products for adults for enhanced calcium intake.

A condiment food product, such as ketchup, mayonnaise or mustard, designed nutritionally for adults. The condiment product, such as ketchup, has several percents of oils or fats, all or most are **InFat**, thus ensuring that while eating such condiment product the adult will not lose valuable calcium. Such product may include 0.5 to 15% fat or oil, preferably 2 to 7%.

Example 16: Cooking oils/fats for adults for enhanced calcium intake.

A cooking oil or fat spread product designed nutritionally for adults. The cooking oil or fat spread product has several percents of oils or fats, all or most are **InFat**, thus ensuring that while eating such oil or spread product the adult will not lose valuable calcium. Such product may include 15 to 100% fat or oil, preferably 60 to 95%.

Example 17: Condiment products for adults for enhanced calcium intake.

A condiment food product, such as ketchup, mayonnaise or mustard, designed nutritionally for adults. The condiment product, such as ketchup, has several percents of oils or fats, all or most are **InFat**, thus ensuring that while eating such condiment product the adult will not lose valuable calcium. Such product may include 0.5 to 15% fat or oil, preferably 2 to 7%. The condiment product is also enriched with calcium, such as calcium phosphate or calcium picolinate, at levels of 0.1% to 5%, preferably 0.5% to 1.5%.

Claims:

1. A dietary ingredient comprising an edible lipid, wherein said lipid is a mimetic substitute of human breast milk having the property of enhancing the absorption of calcium.
2. The dietary ingredient of claim 1, optionally further comprising calcium.
3. The dietary ingredient of claim 1 or 2, further comprising at least one of additives, emulsifiers or carriers.
4. The dietary ingredient of claim 1 or 2, for use in the prevention and/or treatment of disorders associated with any one of depletion of bone calcium and bone density.
5. The dietary ingredient of claim 5, for use in the prevention and/or treatment of osteoporosis.
6. The dietary ingredient of claim 2, for use in the enhancement of bone formation.
7. The dietary ingredient of claim 7, for use in the enhancement of bone formation in infants and young children.
8. The dietary ingredient of claim 2, for use in the enhancement of energy intake by infants and children.
9. A food article comprising the dietary ingredient of any one of the preceding claims.
10. The food article of claim 9, wherein said food article may be selected from infant formula, biscuits and pastries, dairy products, cereal products, prepared foods for infants and young children, condiment products, cooking oils and fats, meat products and prepared foods for adults.

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